

| Instructions: | |
|--|------------------------|
| 1. Complete for each, single award. | |
| 2. For Contracts, Purchase (Requisition) & Task Orders, Modifications | |
| a. Complete Parts A and B. b. Submit to PGO with RFC (Request for Contract), purchase (requisition) request, task order re request. c. Note: Some information requested in Part B may not be available until an award is made. | equest or modification |
| 3. For Grants and Cooperative Agreements | |
| a. Complete Part A. b. Complete Part B or C. c. Submit with funding memorandum. 4. Documentation of exemption criteria and definition of engaged in research for determining per attached. | formance sites are |
| Part A: Complete for each award. (Complete applicable items) | |
| CIO (Include Division/Office) Purchase Order (Requisition) No., Contract No., Task Order No (include contract no.), Modification No. (include contract no.) | |
| Award Number Program Announcement No. | |
| Title of Project GrantCooperative Agreement | |
| Name of CIO Project Officer/Program Official: | |
| Telephone Number: Mailstop: | |
| Project <u>is</u> research involving human participants? <u>If no</u>, state specific reasons, and skip to signatures. | []Yes []No |
| 2. Is the entire project research? <u>If yes</u> , complete Part B of this form. <u>If no</u> , identify each of the research activities involving human participants in Part C of this form. | [] Yes [] No |
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| Part B: | Complete When Entire Award is Research. | | |
|---------|---|-----------------------|------------------|
| 1. | Is award lacking definite research plans? If yes, when is the plan(s) or protocol anticipated Skip to signatures. (estimate time) | []Yes | [] No |
| 2. | Are any CDC scientists participating in the research as co-investigators? If yes, has the project been reviewed at CDC for human subjects protection? List the CDC human subject protocol number and date of most recent approval: | [] Yes Yes [] No | [] No |
| | Protocol number: Date of most recent approval: | | |
| 3. | Is this activity exempt under one of the 6 exemptions in 45 CFR 46? If yes, provide exemption no** | [] Yes | [] No |
| 4. | Is there more than one site engaged in the research? <u>If yes</u> , list all sites by organization name that are engaged in the research. | [] Yes | [] No |
| 5. | Is a human subjects restriction required on the notice of award? If yes, identify the reason for the human subjects restriction, and the amount of funds to be restricted. | []Yes | [] No |
| Needed) | each of the research activities involving human participants by title and answer each que | | es as |
| 1. | Is activity lacking definite research plans? If yes, when is the plan(s) or protocol anticipated (estimate time) | [] Yes | [] No |
| 2. | Are any CDC scientists participating in the research as co-investigators? <u>If yes.</u> has the project been reviewed at CDC for human subjects protection? List the CDC human subjects protocol number and date of most recent approval: | | [] No [] No |
| | Protocol number: Date of most recent approval: | | |
| 3. | Is this activity exempt under one of the 6 exemptions in 45 CFR 46? If yes, provide exemption no** | [] Yes | [] No |
| 4. | Is there more than one site engaged in the research? <u>If ves</u> , list all sites by organization name that are engaged in the research. | [] Yes | [] No |
| 5. | Is a human subjects restriction required on the notice of award? <u>If yes</u> , identify the reason for the human subjects restriction, and the amount of funds to be restricted. | [] Yes | [] No |
| | Page 2 | | |



| (2) (T | itle) | | | | |
|--------|--|-----|----------------|----|----|
| 1. | Is the activity lacking definite research plans? If yes, when is the plan(s) or protocol anticipated | [] | Yes | [] | No |
| 2. | (estimate time) Are any CDC scientists participating in the research as co-investigators? If ves, has the project been reviewed at CDC for human subjects protection? List the CDC human subjects protocol number and date of most recent approval: | |] Yes] Yes | | |
| | Protocol number: Date of most recent approval: | | | | |
| 3. | Is this activity exempt under one of the 6 exemptions in 45 CFR 46? <u>If yes</u> , provide exemption no. | [|] Yes | [] | No |
| 4. | Is there more than one site engaged in the research? If yes, list all sites by organization name that are engaged in the research. | 1 |] Yes | [] | No |
| 5. | Is a human subjects restriction required on the notice of award? <u>If ves</u> , identify the reason for the human subjects restriction, and the amount of funds to be restricted. |] |] Yes | [] | No |
| (3) (T | itle) | | | | |
| 1. | Is the activity lacking definite research plans? If yes, when is the plan(s) or protocol anticipated (estimate time) | [] | Yes | [] | No |
| 2. | Are any CDC scientists participating in the research as co-investigators? If ves, has the project been reviewed at CDC for human subjects protection? List the CDC human subjects protocol number and date of most recent approval: | |] Yes] Yes | | |
| | Protocol number: Date of most recent approval: | | | | |
| 3. | Is this activity exempt under one of the 6 exemptions in 45 CFR 46? <u>If yes</u> , provide exemption no. | [] |] Yes | [] | No |
| 4. | Is there more than one site engaged in the research? If yes, list all sites by organization name that are engaged in the research. | [] | Yes | [] | No |
| 5. | Is a human subjects restriction required on the notice of award? | [| Yes | [] | No |
| | If yes, identify the reason for the human subjects restriction, and the amount of funds to be restricted. | | | | |



| APPROVALS (Signature and Position Title) | Date | Remarks | |
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| D 1 4 OCC /D OCC 1 | | | |
| Project Officer/Program Official | | | |
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| Branch Chief or Branch ADS | | | |
| | | | |
| | | | |
| Division ADS or Human Subjects Contact | | | |
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| CIO (II | | | |
| CIO (Human Subjects Contact) | | | |
| CDC/ATSDR | | | |
| Deputy Associate Director for Science | | | |

^{**}If an exemption is claimed, PGO will promptly forward this form and the application via interoffice mail to the CDC/ATSDR Deputy Associate Director for Science.